

**From:** Grant Duque [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85F9EA2FED1C48928E5ED4567D97D39A-GRANT DUQUE]  
**Sent:** 3/21/2019 4:36:47 PM  
**To:** Joshua Chaidez [Josh.Chaidez@intusurg.com]; Radit Tantisira [Radit.Tantisira@intusurg.com]; Harsukh Ratia [Harsukh.Ratia@intusurg.com]; Nhut Diep [Nhut.Diep@intusurg.com]; Shark Somayaji [Shark.Somayaji@intusurg.com]; Matt Ohline [Matt.Ohline@intusurg.com]; Linda Young [Linda.Young@intusurg.com]; Mark Veeh [Mark.Veeh@intusurg.com]; Alejandro de la Fuente Vornbrock [Alejandro.Delafuente@intusurg.com]  
**CC:** Charlie Dean [Charlie.Dean@intusurg.com]; Shreya Purohit [Shreya.Purohit@intusurg.com]; Todd Tourand [Todd.Tourand@intusurg.com]; Anthony McGrogan [Anthony.McGrogan@intusurg.com]; Todd Radgowski [Todd.Radgowski@intusurg.com]  
**Subject:** RE: Skywalker Pre-Go Active debrief & next steps  
**Attachments:** RMA and Reliability Predictions\_TL\_AS\_02.pptx; COGS Xi 8mm.xlsx; ATT68701; ATT55417

All,

Thanks for being patient as I revisited the COGs numbers we want to set for baseline. I had to get Shark's help to weed through some of the SAP errors.



COGS Xi  
8mm.xlsx

The last check-in on COGs was this (we verified are accurate for what we ship today):

Inst	SKU - ver	COGs
LND	470006-12	140
MSCND	470309-14	200
Cadiere	470049-06	146
ProGrasp	470093-11	134
MBF	470172-16	160
FBF	470205-17	144

If we take the snapshot of SKU versions that were being shipped +3 years post launch(April 2017), these are the COGs for each SKU:

Inst	SKU - ver	COGs
LND	470006-10	137
MSCND	470309-12	201
Cadiere	470049-04	146
ProGrasp	470093-09	129
MBF	470172-14	169
FBF	470205-14	169

We actually had slightly lower costs for LND and ProGrasp, and insignificant differences for MSCND and Cadiere. Some of the recent reliability improvements have increased component costs associated w/ them. For both Bipolar instrument, the +3 post-launch cost was 169. It wasn't until very recently that we lowered the cost w/ the new overmolded grips and lower cost cables.

Based on this I'm proposing that we stick w/ the current COGs that we have today, with perhaps some leniency on Bipolar (use 169 for both FBF/MBF). The concern on bipolar is that we may need to add cost back in to ensure reliability of the grips.

Baseline



Inst	SKU - ver	COGs	1.25X	1.5X	1.75X	2X
LND	470006-12	140	175	210	245	280
MSCND	470309-14	200	250	300	350	400
Cadiere	470049-06	146	183	219	256	292
ProGrasp	470093-11	134	168	201	235	268
MBF	470172-16	169	211	254	296	338
FBF	470205-17	169	211	254	296	338

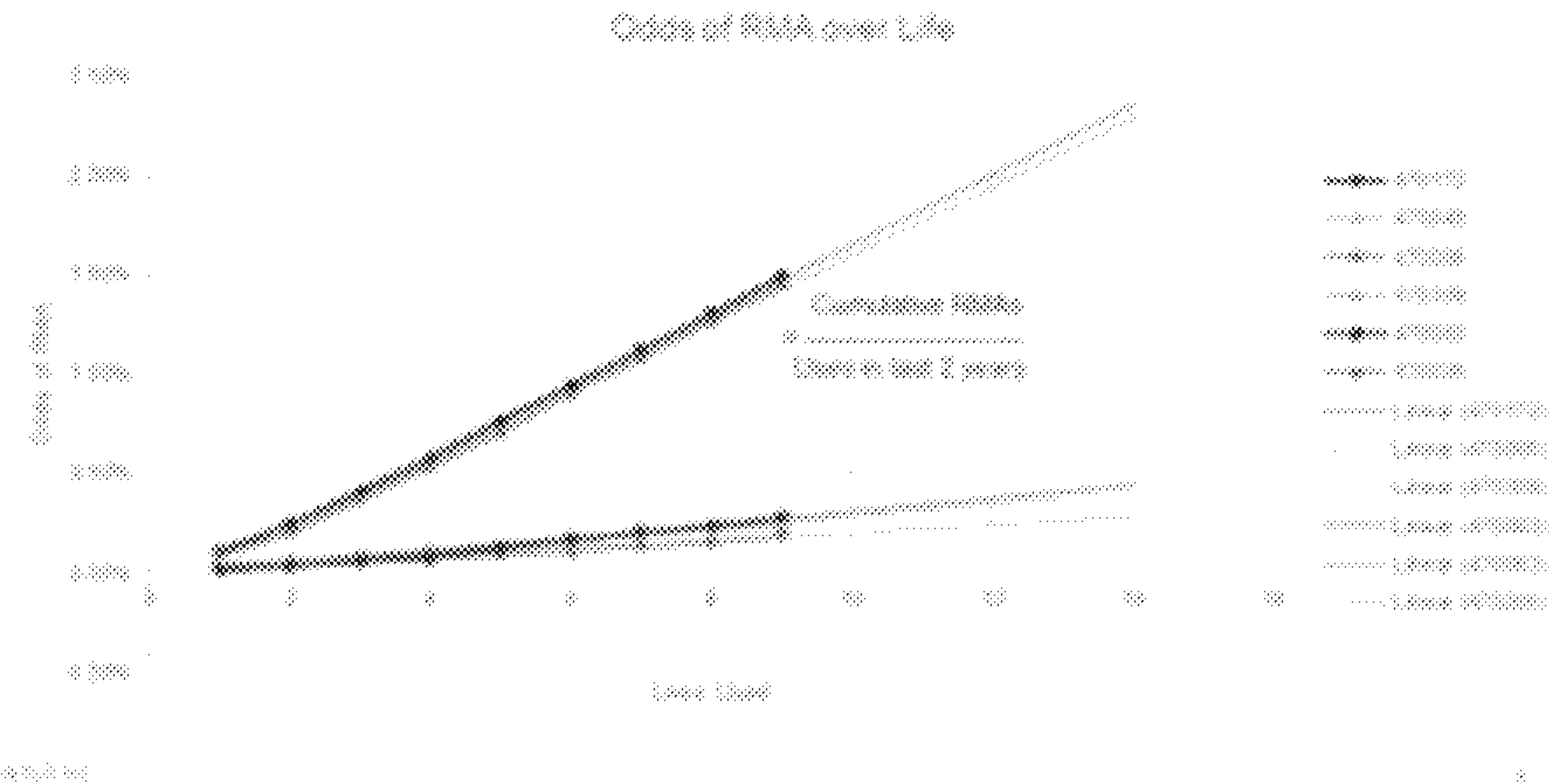
Radit, I'll find you to incorporate this into your Project Charter with Minimal, Nominal, and Best scenarios slide. Notice that I've already included 1.75X and 2X.

Regarding lives, I've attached the field data analysis that was done as part of the Core Instrument life extension project.

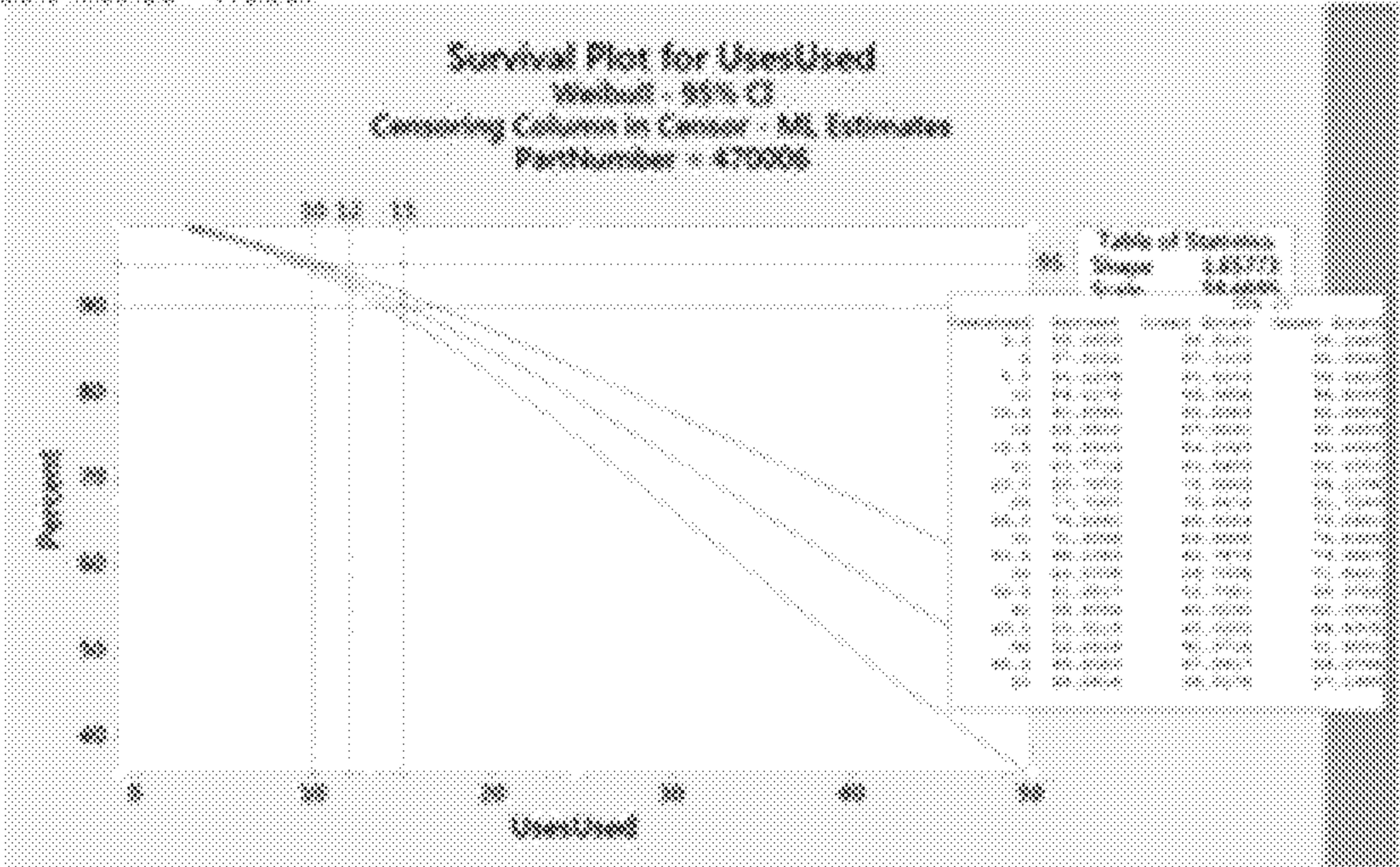
Bottom line, statistical modelling of our current Xi Core Instruments field data supports >90% reliability (w/ relatively high confidence) even if we extend lives to 15. (12 lives for MBF)

Odds of RMA

Linear predictions by instrument



Parametric Method - Weibull



RMA and Reliability Predict...

I'll share an excerpt and summary of these findings for the Cross BU GoActive meeting.

-grant

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**From:** Joshua Chaidez <Josh.Chaidez@intusurg.com>

**Sent:** Thursday, March 21, 2019 9:17 AM

**To:** Radit Tantisira <Radit.tantisira@intusurg.com>; Grant Duque <Grant.Duque@intusurg.com>; Harsukh Ratia <Harsukh.Ratia@intusurg.com>; Nhut Diep <Nhut.Diep@intusurg.com>; Shark Somayaji <Shark.Somayaji@intusurg.com>; Matt Ohline <Matt.Offline@intusurg.com>; Linda Young <Linda.Young@intusurg.com>; Mark Veeh <Mark.Veeh@intusurg.com>; Alejandro de la Fuente Vornbrock <Alejandro.DelaFuente@intusurg.com>

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**Subject:** RE: Skywalker Pre-Go Active debrief & next steps

Radit,

Good Meeting. Feedback/Questions:

- Minimal Column Cost/Use – stated is 'same as nominal'. However the lives are 10 in minimal and 12 in nominal. The cost at 10 lives would be higher, perhaps ~2x depending on Grant's baseline, correct?
- Also, I recall the 1.5x required 15/12. Is the best 1.5x a reasonable stretch if lives are 12/10?
- Should the ASP premium be noted in the contract? This is more relevant for margin analysis, which I realize is not the primary focus of the contract, however, it does impact the forecast assumptions.
- Is the forecast based on refurbishment in year 2 and beyond? If yes, should we consider a forecast with no refurbishment since this is TBD awaiting the financial assessment results. Just want to make sure we drive the correct focus on mfg ramp/supplier capacity timing.

Josh

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**From:** Radit Tantisira <Radit.tantisira@intusurg.com>

**Sent:** Wednesday, March 20, 2019 5:15 PM

**To:** Grant Duque <Grant.Duque@intusurg.com>; Harsukh Ratia <Harsukh.Ratia@intusurg.com>; Nhut Diep <Nhut.Diep@intusurg.com>; Shark Somayaji <Shark.Somayaji@intusurg.com>; Matt Ohline <Matt.Offline@intusurg.com>; Joshua Chaidez <Josh.Chaidez@intusurg.com>; Linda Young <Linda.Young@intusurg.com>; Mark Veeh <Mark.Veeh@intusurg.com>; Alejandro de la Fuente Vornbrock <Alejandro.DelaFuente@intusurg.com>

**Cc:** Charlie Dean <Charlie.Dean@intusurg.com>; Shreya Purohit <Shreya.Purohit@intusurg.com>; Todd Tourand <Todd.Tourand@intusurg.com>; Anthony McGrogan <Anthony.McGrogan@intusurg.com>; Todd Radgowski <Todd.Radgowski@intusurg.com>

**Subject:** RE: Skywalker Pre-Go Active debrief & next steps

Hi all. Thanks for making the time to talk through a modified Skywalker Project Charter that focuses on 3 scenarios at mature volumes (~100k/yr).

Here's an initial project charter draft that consolidates our conversation into the 3 different scenarios.

- Establishing cost/use target
- Grant to provide historical base 8mm Xi product cost at 3 year maturity
- Nominal scenario multiplies this cost x 1.50
- Best scenario multiplies this cost x 1.25
- Financial summary – Linda, looking for your help to run 3 different financial scenarios according to the Minimal, Nominal, Best assumptions



- We will have to revise Shreya’s forecast by assuming the number of instrument lives in the first year. 2<sup>nd</sup> year lives for all scenarios can be assumed to be 12 and 15.
- SV manufacturing for 1<sup>st</sup> year of launch. 2<sup>nd</sup> year in MX.
- Partial in-source of sensor assemblies at launch with 1<sup>st</sup> year of assembly also in SV. This labor rate increase affects the sensor cost assumption. This requires additional AET resources to support.
- **Nhut/Grant**, can you help consolidate the revised costs assuming SV manufacturing of partial in-source and instrument?
- Eliminate the fully outsourced scenario from NLE
- Refurbishment requires (at a minimum) additional assessment to determine financial viability. I left in Nominal and Best goals for now.
- For the financial summary, I think we can add refurbishment into the Best scenario.
- Shreya, I’m still assuming Xi/X compatible without FFB function although that was raised as a question in today’s user facing meeting.

Please review and provide your input. Thanks.  
Radit

Topics	Minimal	Nominal	
Instrument Scope	Same as nominal	Add FFB to 6 instruments: •LND, MSCND •Prograsp, Cadiere •MBF, FBF Xi/X compatible without FFB function	Nominal set with <b>Force Bipolar</b> replacing FBF
Product Cost Target at ~100k vol/yr •Cost/use  •Instrument lives  •Refurbishment	Same as nominal  10 lives / instrument on needle drivers, cold graspers, and bipolar instruments Assess financial viability of refurbishment program	Grant to provide historical base 8mm Xi product cost at 3yr maturity X 1.50  12 lives / instrument on needle drivers and cold graspers 10 lives / instrument on bipolar instruments Process defined for instrument teardown and rebuild Logistics process defined for collection	Grant to provide historical base 8mm Xi product cost at 3yr maturity X 1.25 15 lives / instrument for needle drivers and cold graspers 12 lives / instrument for bipolar  Qualified for 1 refurb cycle for a same number of lives/instrument at launch
Financial summary (SV mfg 1 <sup>st</sup> year, 12/15 lives by 2 <sup>nd</sup> year, sensor assy partial in-source at launch, full in-source at 100k)	No refurbishment  NPV	No refurbishment  NPV	+ Refurbishment  NPV
<u>Schedule</u> Regulatory Submit First Case - <i>Country</i> Full Launch – <i>Country</i>	FL US ≤ 5Q after O2 US FL  +1Q: Traditional 510(k) submit = Q2 2021 FC (OUS/US) = Q2 2022 FL US = Q2 2022	FL US ≤ 4Q after O2 US FL  Traditional 510(k) submit = Q1 2021 FC OUS or US = Q1 2022 FL US = Q1 2022	FL US ≤ 3Q after O2 US FL  -1Q: Traditional 510(k) submit = Q4 2020 FC OUS or US = Q4 2021 FL US = Q4 2021
<u>Project Cost</u> Current Baseline Current Year Budget	+20%: Total project budget = \$34.6M 2019 budget = \$3.5M	Total project budget = \$28.8M 2019 expense budget = \$2.9M	-20%: Total project budget = \$23.0M 2019 budget = \$2.3M

-----Original Appointment-----  
**From:** Radit Tantisira  
**Sent:** Tuesday, March 19, 2019 3:44 PM  
**To:** Radit Tantisira; Grant Duque; Harsukh Ratia; Nhut Diep; Shark Somayaji; Matt Ohline; Joshua Chaidez; Linda Young; Mark Veeh  
**Cc:** Charlie Dean; Alejandro de la Fuente Vornbrock  
**Subject:** Skywalker Pre-Go Active debrief & next steps

**When:** Wednesday, March 20, 2019 3:00 PM-4:00 PM (UTC-08:00) Pacific Time (US & Canada).

**Where:** CR-SV-B1090.2 Core Instrs

First of perhaps several smaller meetings to discuss Skywalker Go Active prep. I know some of you aren't available for this meeting, but I wanted to meet sooner rather than later to get initial thoughts.

1. Discuss scenario planning and assumptions we should make to establish the minimum requirements to launch. What different financial models should we create?

2. How should the presentation change for next week's cross BU Go Active meeting? Audience is Bob and staff and Brian and staff.

My initial thoughts on scenarios and assumptions:

- At launch: 10k volume pricing, 10/12 lives, partial sensor in-source = MINIMUM TO LAUNCH?
- 1yr post launch: 40k volume pricing, 12/15 lives, partial sensor in-source
- 4yr post launch: 100k volume pricing, 12/15 lives; full sensor in-source

--- Do not delete or change any of the following text. ---

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